

# EXHIBIT A

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8 UNITED STATES DISTRICT COURT  
9 DISTRICT OF NEVADA  
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11 STATE OF NEVADA, ) 3:05-cv-00322-HDM-RAM  
12 EX REL. H. DEAN STEINKE )  
13 Relator )  
14 ) ORDER  
15 Plaintiffs, )  
16 v. )  
17 MERCK & CO., INC., )  
18 Defendant. )  
19

20 Before the court is defendant's Motion to Dismiss Plaintiffs'  
21 Amended Complaint (#34). Plaintiffs filed an opposition (#38).  
22 The states of California, Delaware, Illinois, Texas, and the  
23 District of Columbia have filed an amici curiae brief in opposition  
24 to the motion (#41). Defendants replied (#49). Defendants filed a  
25 response to the amicus curiae brief (#54).

26 I. BACKGROUND

27 This is a *qui tam* action brought under the Nevada False Claims  
28 Act, N.R.S. § 357.010 et seq., for Merck's alleged failure to  
include certain discounted and free Zocor and Vioxx products in the  
"Best Price" reports Merck submitted to the federal government

1 pursuant to the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8.

2       The complaint alleges that Merck failed to include discounts  
3 under the Simvastatin Acute Care Value Enhancement ("SAVE") program  
4 for Zocor. The program provided discounts of up to 92% from the  
5 catalog price for Zocor if a hospital maintained a 70% market share  
6 or established Zocor as the exclusive statin drug on its formulary.

7       The complaint also alleges that Merck failed to include a 92%  
8 discount for Vioxx under the Vioxx Incentive Program ("VIP") if a  
9 hospital committed to maintain an 80% market share.

10       Lastly the complaint alleges that Merck gave away free goods  
11 to "effectively lower" the price that Merck charged providers for  
12 these pharmaceuticals.

13 **II. MOTION TO DISMISS**

14 **A. FAILURE TO STATE A CLAIM - 12(b) (6)**

15       In considering a motion to dismiss for failure to state a  
16 claim under Fed.R.Civ.P. 12(b) (6), the court must accept as true  
17 all material allegations in the complaint as well as all reasonable  
18 inferences that may be drawn from such allegations. *LSO, Ltd. v.*  
19 *Stroh*, 205 F.3d 1146, 1150 (9th Cir. 2000). The allegations of the  
20 complaint also must be construed in the light most favorable to the  
21 nonmoving party. *Shwarz v. United States*, 234 F.3d 428, 435 (9th  
22 Cir. 2000). The purpose of a motion to dismiss under Rule 12(b) (6)  
23 is to test the legal sufficiency of the complaint. *Navarro v.*  
24 *Block*, 253 F.3d 729, 732 (9th Cir. 2001). The court can grant the  
25 motion only if it is certain that the plaintiff will not be  
26 entitled to relief under any set of facts that could be proven  
27 under the allegations of the complaint. *Cahill v. Liberty Mut.*  
28 *Ins. Co.*, 80 F.3d 336, 338 (9th Cir. 1996).

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2 **B. ANALYSIS**

3 Merck makes four arguments for dismissal under Rule 12(b)(6):

4 (1) Plaintiffs have misread the relevant portion of the Rebate  
5 Statute and Rebate Agreement, (2) Merck's Best Price reports are not  
6 "knowingly" false as a matter of law, (3) the claims are barred  
7 under the doctrine of conflict preemption, and (4) Plaintiffs have  
8 not satisfied the heightened pleading requirements under Rule 9(b).  
9 The court will address each contention in turn.

10 **C. MISREADING THE REBATE STATUTE AND AGREEMENT**

11 Merck contends that under a proper reading of the Rebate  
12 Statute, Nevada has not pled facts that would create a cause of  
13 action under the Nevada False Claims Act.

14 "In construing a statute, we first consider its text. When the  
15 statute's language is plain, the sole function of the courts -- at  
16 least where the disposition required by the text is not absurd --  
17 is to enforce it according to its terms." *In re County of Orange*,  
18 262 F.3d 1014, 1018 (9th Cir. 2001). A "cardinal principle of  
19 statutory construction [is] that we must give effect, if possible,  
20 to every clause and word of a statute." *Williams v. Taylor*, 529  
21 U.S. 362, 404 (2000) (internal quotations omitted). The court is  
22 thus "reluctant to treat statutory terms as surplusage in any  
23 setting." *Duncan v. Walker*, 533 U.S. 167, 174 (2001).

24 However, if an agency is responsible for administering a  
25 statute, the court confronts two questions when reviewing the  
26 agency's interpretation. First, the court must determine if  
27 "Congress has directly spoken to the precise question at issue. If  
28 the intent of Congress is clear, that is the end of the matter; for

1 the court, as well as the agency, must give effect to the  
2 unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc.*  
3 *v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). If Congress has not  
4 directly addressed the question and the agency has made an  
5 administrative determination, the court must determine if "the  
6 agency's answer is based on a permissible construction of the  
7 statute." *Id.*

8 Congress defined "best price" as:

9 [T]he lowest price available from the manufacturer  
10 during the rebate period to any wholesaler, retailer,  
11 provider, health maintenance organization, nonprofit  
12 entity, or governmental entity within the United States,  
13 excluding [certain governmental entities not applicable  
14 to this case.]

15 42 U.S.C. § 1396r-8(c)(1)(C)(i).

16 Congress expressly provided some "special rules" to be used in  
17 the calculation of "best price."

18 The term best price --

19 (I) shall be inclusive of cash discounts,  
20 free goods that are contingent on any purchase  
21 requirement, volume discounts, and rebates (other than  
22 rebates under this section);

23 ... and

24 (III) shall not take into account prices  
25 that are merely nominal in amount.

26 42 USCS § 1396r-8(c)(1)(C)(ii).

27 Under the statute, the Secretary of Health and Human Services  
28 is given broad enforcement powers. See e.g. § 1396-r8(b)(3)(B),

1 §1396-r8(b)(3)(C). In addition, the Secretary promulgates  
2 regulations and interpretations for the program through the Centers  
3 for Medicare and Medicaid Services ("CMS").

4 Merck urges the court to adopt a reading of the best price  
5 statute as to exclude any prices less than 10% of the Average  
6 Manufacturer's Price ("AMP"). In support of this interpretation,  
7 Merck cites to the Rebate Agreement which defined "nominal price"  
8 as "any price less than 10% of the AMP in the same quarter for  
9 which the AMP is computed." Rebate Agreement, § I(s). Merck  
10 claims this is consistent with the CMS release of December 14, 1994  
11 which states in part, "any prices that are nominal in amount, that  
12 is, less than 10% of the AMP ... are excluded from the best price  
13 calculation." CMS release No. 14 (1994).

14 Nevada maintains that such a reading would render part (I) of  
15 the special exceptions section superfluous as any free good would  
16 be, by definition, less than 10% of the AMP. Nevada contends the  
17 proper interpretation of "best price" is to include cash discounts,  
18 free goods that are contingent on any purchase requirement, volume  
19 discounts, and rebates if the price of those goods is less than 10%  
20 of the AMP and those prices are tied to a purchase agreement.

21 The congressional record addresses what prices should be  
22 excluded under the "best price" statute. The exclusion of "prices  
23 that are merely nominal" was intended to exclude those prices that  
24 "manufacturers offer to special purchasers, such as the sale of  
25 birth control pills for a penny a pack to Planned Parenthood." 136  
26 Cong. Rec. S 12954, \*S12962 (1990). Likewise the legislative  
27 history shows that the Rebate Statute was intended to ensure that  
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1 Medicaid was "to receive the best discounts in the market...." *Id.*  
2 at \*S12954.

3 The legislative history shows no material change between the  
4 bill as enacted and the bill as introduced for the computation of  
5 "best price."<sup>1</sup>

6 Nevada also urges the court to give meaning to the word  
7 "merely" as used in subsection III of the "special rules" section  
8 of the Rebate Statute. The Oxford English Dictionary defines  
9 "merely" as

- 10 1. a. Without admixture or qualification; purely;  
11 exclusively.
- 12 b. Without the help of others; solely.
- 13 2. a. Absolutely, entirely; quite, altogether.
- 14 b. As a matter of fact, actually.
- 15 3. Without any other quality, reason, purpose,  
16 view, etc.; only (what is referred to) and nothing  
17 more.

18 Oxford English Dictionary Online at <http://dictionary.oed.com>  
19 (2006). Thus, Nevada contends that the phrase "prices that are  
20 merely nominal in amount" relate to prices that are without  
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23 The change from "lowest price" to "best price" is a change in  
24 nomenclature that does not affect the analysis of how the "best price"  
25 is defined under the statute. The addition of the parenthetical  
26 phrase "other than rebates under this section" indicates the intent  
27 to exclude from the calculation of "best price" rebates paid under S  
28 1396r-8, which is not at issue in this case.

1 qualifications; to do otherwise would render the qualifier "merely"  
2 as surplusage.

3 Nevada's interpretation is consistent with a letter from CMS  
4 Administrator, Mark McClellan, to W.J. "Billy" Tauzin, President  
5 and CEO of the Pharmaceutical Research and Manufacturers of  
6 America, regarding the giveaway of free drugs to help those  
7 affected by the Hurricane Katrina disaster. Mr. McClellan states  
8 in his letter, "[u]nder the plain terms of the Medicaid statute,  
9 free goods 'that are contingent on any purchase requirement' must  
10 be included in the calculation of the best price." Ex. E to  
11 Defendant's Motion.

12 This interpretation is also consistent with CMS release No. 14  
13 which stated:

14 "best price data '... must be adjusted by the  
15 Manufacturer if ... other arrangements subsequently  
16 adjust the prices actually realized.' Thus, we consider  
17 any price adjustment which ultimately affects the price  
18 actually realized by the manufacturer as 'other  
19 arrangements' and, as required by the rebate agreement,  
20 included in the calculations of AMP and best price."

21 CMS Release No. 14 at 1 (1994).

22 This court concludes that the phrase "prices that are merely  
23 nominal in amount" is "all prices that are less than 10% of the  
24 AMP, but without other qualifications." This interpretation gives  
25 deference to the Secretary's interpretation of "nominal price" and  
26 also gives meaning to the word "merely" contained in the statute.  
27 A "merely nominal price" is a price that is less than 10% of the  
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1 AMP and is not tied to other conditions of performance or  
2 consideration in addition to the "nominal prices."

3 It is undisputed that Merck did not include prices tied to its  
4 SAVE and VIP incentive programs in its calculation of best price.  
5 The SAVE and VIP discount and marketing plans described in the  
6 complaint required additional valuable consideration and conditions  
7 precedent that were more than a "merely nominal price." Therefore,  
8 these prices are not without qualification.<sup>7</sup>

9 **D. MERCK'S REPORTS**

10 Merck next urges that it cannot be found to have acted  
11 knowingly for purposes of the False Claims Act ("FCA") as a matter  
12 of law because Merck complied with the express terms of the Rebate  
13 Agreement. Further, Merck contends that even if the reports were  
14 false, it is based on both an honest mistake and a reasonable  
15 interpretation and cannot be "knowingly false" as required by the  
16 FCA.

17 Nevada responds by contending that Merck failed to comply with  
18 the express terms of Rebate Agreement by omitting the prices for  
19 free and discounted goods under the VIP and SAVE incentive plans.  
20 Nevada argues that whether Merck acted reasonably is a factual  
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22 <sup>7</sup>Merck concedes that the definition of "merely" means "nothing  
23 else or more; only." Thus, Merck proposes the definition of "merely  
24 nominal" to be "only nominal in amount" or "nothing more than nominal  
25 in amount." See # 49 at fn 5. Even if the court were to accept  
26 Merck's definition, the prices are tied to incentive programs and are  
27 not "only nominal in amount" nor "nothing more than nominal in  
28 amount."

1 question that must be resolved at trial and not on a motion to  
2 dismiss.

3 For purposes of the Nevada FCA, a person acts knowingly if the  
4 person "(a) has knowledge of the information; (b) acts in deliberate  
5 ignorance of whether the information is true or false; or (c) Acts  
6 in reckless disregard of the truth or falsity of the information."  
7 N.R.S. § 357.040(2).

8 The Nevada Supreme Court has held that the scienter  
9 requirement in the FCA requires the "knowing presentation of what  
10 is known to be false." *Int'l Game Tech. v. Second Judicial Dist.*  
11 *Court*, 127 P.3d 1088, 1105 (Nev. 2006). It does not mean "to take  
12 advantage of a disputed legal question." *Id.* This is to avoid  
13 punishing "honest mistakes or incorrect claims submitted through  
14 mere negligence." *Id.*

15 As the court explains later in the opinion, the "FCA is meant  
16 to encourage private persons to reveal instances when a person has  
17 cheated or attempts to cheat the government by submitting documents  
18 containing manufactured or omitted facts or data." *Id.* at 1106

19 A reasonable interpretation does not render a statement "not  
20 false," but rather the good faith nature of the action "forecloses  
21 the possibility that the scienter requirement is met." *United*  
22 *States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir.  
23 1999).

24 Nevada has alleged that by omitting the prices of free and  
25 discounted drugs given to hospitals as part of Merck's incentive  
26 plans in the best price reports Merck did not act reasonably in  
27 failing to comply with the terms of the Rebate Agreement. On the  
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1 basis of the pleadings the court cannot conclude as a matter of law  
2 that Nevada has failed to allege a claim under the FCA.

3 **E. CONFLICT PREEMPTION**

4 Merck also argues that the doctrine of conflict preemption  
5 precludes this lawsuit. Merck contends that Nevada is seeking to  
6 have its definition of "nominal price" be enforced by the court.  
7 This, Merck says, would create conflicting obligations between the  
8 state and federal requirements. Merck also contends that the fraud  
9 claim is precluded under *Buckman Co. V. Plaintiffs' Legal Comm.*,  
10 531 U.S. 341 (2001).

11 Nevada responds by contending the state is not seeking to have  
12 its definition of "nominal price" enforced, rather Nevada is  
13 seeking to enforce the Rebate Statue. In addition, Nevada  
14 responds, the Rebate Statue provides statutory remedies that are  
15 "in addition to other penalties as may be prescribed by law." 42  
16 U.S.C. § 1396r-8(b)(3)(C)(ii).

17 A state law claim is invalidated if "compliance with both  
18 federal and state regulations is a physical impossibility" or when  
19 "state law stands as an obstacle to the accomplishment and  
20 execution of the full purposes and objectives of Congress."  
21 *Siuslaw Concrete Constr. Co. v. Washington, Dep't of Transp.*, 784  
22 F.2d 952, 955 (9th Cir. 1986).

23 Instructive on the preemption analysis is the decision in re  
24 *Pharm. Indus. Average Wholesale Price Litig.*, 321 F.Supp.2d 187 (D.  
25 Mass. 2004) ("PhARM IV"). In that case, the court found that  
26 Congress did not have a clear and manifest purpose to preempt state  
27 law when it passed the Rebate Statue. *PhARM IV* at 198. Rather,  
28 the court found that Medicaid is an example of cooperative

1 federalism and "that matters of public health and medical fee  
2 regulation have been a field traditionally occupied by the states,  
3 and states have historically played a significant role in  
4 investigating and prosecuting Medicaid fraud." *Id.*

5 In distinguishing *Buckman* the court found that because  
6 *Buckman* claimed fraud on an agency of the United States and because  
7 United States agencies are "uniquely federal" there is no state  
8 interest in such circumstances. *Pharm IV* at 198.

9 *Buckman* involved state-law causes of actions based on claims  
10 that the defendant made fraudulent representations to the FDA as to  
11 the intended use of the bone screws and that, as a result, the  
12 devices were improperly given market clearance and were  
13 subsequently used to the plaintiffs' detriment. The Supreme Court  
14 held that the claims were preempted because the "federal statutory  
15 scheme amply empowers the FDA to punish and deter fraud against the  
16 Agency, and that this authority is used by the Agency to achieve a  
17 somewhat delicate balance of statutory objectives." *Buckman* at  
18 347. Unlike *Buckman*, the "Secretary does not make an independent  
19 determination with respect to Best Price, but merely acts as a  
20 go-between." *PhARM* at 199.

21 Second, the court found the statute at issue in *Buckman*  
22 expressly gave the federal government, not private litigants, the  
23 power to file suit for non-compliance, "whereas here the [Rebate]  
24 statute provides that the federal remedies are 'in addition to  
25 other penalties as may be prescribed by law.'" *Id.*

26 The court also found that the "United States considers the  
27 Best Prices statute to be one of cooperative federalism and does  
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1 not seek the right to exclusive rebate enforcement power."<sup>3</sup> *Id.*  
2 Therefore, the court concluded that there is no "unique federal  
3 interest" to be upset by allowing states to pursue claims under the  
4 Best Price statute. *Id.* at 200.

5 Merck has failed to show that the Nevada state law requiring  
6 compliance with the Rebate Statute causes conflicting requirements  
7 between state law and federal law. Merck has also failed to show  
8 that the FCA stands as an obstacle to the accomplishment and  
9 execution of the full purposes and objectives of Congress when the  
10 United States has expressly disclaimed the necessity for exclusive  
11 enforcement powers under the Rebate Statute. Accordingly, the  
12 court concludes that the doctrine of conflict preemption does not  
13 bar this lawsuit.

14 **F. FAILURE TO PLEAD WITH PARTICULARITY 9(b)**

15 Merck lastly contends that Nevada has failed to plead fraud  
16 with particularity as required by Fed. R. Civ. P. 9(b). If a  
17 plaintiff makes an allegation of fraud or mistake, "the  
18 circumstances constituting fraud or mistake shall be stated with  
19 particularity." However, "[m]alice, intent, knowledge, and other  
20 condition of mind ... may be averred generally." Fed.R.Civ.P.  
21 9(b). This requirement is satisfied in the plaintiff pleads "(i)  
22 some of the specific customers defrauded, (ii) the type of conduct  
23 at issue, (iii) the general time frame in which the conduct  
24 occurred, and (iv) why the conduct was fraudulent." *United States*

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26 <sup>3</sup>The United States, in a letter addressed to this court, has  
27 stated it agrees with the reasoning in *PhARM IV* on the issue of  
28 conflict preemption. See # 27.

1 *v. Smithkline Beecham Clinical Labs.*, 245 F.3d 1048, 1051 (9th Cir.  
2 2001). The pleading requirement is also relaxed "with respect to  
3 matters within the opposing party's knowledge. In such situations,  
4 plaintiffs can not be expected to have personal knowledge of the  
5 relevant facts." *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir.  
6 1993). Rule 9(b) is therefore satisfied if the complaint provides  
7 notice of the alleged misrepresentations.

8 Here Nevada has pled that it has been defrauded by Merck's  
9 best price reports that failed to take into account free or  
10 discounted pharmaceuticals given to hospitals as part of an  
11 incentive program between 1999 and the present in  
12 violation of the Nevada False Claims Act. The court finds that  
13 this satisfies the requirements of Rule 9(b).

14 **III. CONCLUSION**

15 Accordingly, **IT IS ORDERED** that defendant's Motion to Dismiss  
16 Plaintiffs' Amended Complaint (#34) be **DENIED**.

17 DATED: This 31st day of May, 2006.

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20 UNITED STATES DISTRICT JUDGE  
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